

**REMARKS/ARGUMENTS**

By this Amendment, claims 3-14, 16-17 are canceled, claim 15 is amended, and claim 18 has been added. Claims 1-2, 15, and 18 are pending.

Citations to the Specification are directed to U.S. Patent Application No. 2005/0143432. Support for the amendment to claim 15 can be found throughout the Specification as originally filed, and specifically in ¶[0006]. Support for new claim 18 can be found throughout the Specification as originally filed, and specifically in ¶[0007].

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**Allowable Claim**

Applicant gratefully acknowledges the indication of allowability of claim 1.

**Rejection under 35 U.S.C. 112, second paragraph**

Claim 2 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 2, the Examiner argues that claim 2 recites the limitation "figure 1", and that they therefore fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention. However, incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993). MPEP 23173.05(s). Here, the claims are incorporating the X-ray powder diffraction pattern as set forth in Figure 1. There is not a more concise way to incorporate the data from the X-ray powder diffraction pattern, other than to incorporate the Figures by reference. Since it would be unwieldy to duplicate the Figures into the claims, reconsideration and withdrawal of the rejection is respectfully requested.

**Rejection under 35 U.S.C. 112, first paragraph**

Claim 15 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for crystalline "Form I" of valdecoxib with the specific XRPD found in Figure I and on page 2 of the specification, does not reasonably provide enablement for compositions containing said polymorphic form. The Examiner argues that claim 15 is drafted in terms of a pharmaceutical composition comprising valdecoxib Form 1, and that it is known in the art that polymorphs tend to convert from less stable to more stable forms.

However, claim 15 has been amended to be directed to stable valdecoxib form I. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. United States v. Teletronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 USC 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. In re Marzocchi, 439 F.2d 220, 224, 169 USPO 367, 370 (CCPA 1971).

Here, the claim is enabled because there is not any reason to doubt the objective truth of the statements contained in the Specification for enabling support. The Specification discloses the manner and process for making and using the claimed invention. Applicants disclose a novel stable valdecoxib Form 1 ¶[0007]. In Example 1, Applicants disclose a method of producing valdecoxib Form 1 ¶[0021]. Thus, given the teachings of the Specification, in light of the further experimentation carried out by the Applicant using the disclosed methods, the quantity of experimentation required is not excessive in view of the subject matter of the claims. The Specification sets forth several methods for producing the novel valdecoxib Form 1. Working Examples are also provided, as well as detailed information as to the methods.

Accordingly, reconsideration and withdrawal of the rejection of pending claim 15 as

Application No. 10/510,333  
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lacking enablement is respectfully requested.

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For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

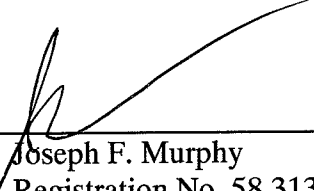
Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
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December 1, 2008

Please charge or credit our  
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